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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ioannis Pallikaris

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7590 11/25/2008
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EXAMINER

NGUYEN, VI X

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

11/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/786,350	Applicant(s) PALLIKARIS ET AL.	
	Examiner Victor X. Nguyen	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,7,8,10-12 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7,8,10-12 and 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/28/08;6/5/08</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The remarks filed 6/27/2008, with respect to claims 1,3,5,7,8,10-12 and 14-23 and the Terminal Disclaimer are acknowledged. However, upon further consideration, a new ground(s) of rejection is made in view of Loomas, Dybbs and Ruiz. Rejections based on the cited reference(s) follows.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. The claimed invention, claims 1,3,5,7,8,10-12 and 14-23 are directed to non-statutory subject matter. For-example, claim 1 positively recites a part of human body, "*a ring seating on the eye* with its plane parallel to a limbus, having an internal diameter " should be replaced with "*a ring is configured to seat on the eye... to a limbus and having an internal diameter* "and **claim 16 recites** "and where the separated epithelial disk *is rolled on the drum*" should be replaced with "and where the separated epithelial disk *is configured to roll on the drum*"

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 recites "where said separator *is not sharp enough to excise corneal tissue* during operation" is indefinite. Applicant uses the term "the separator is not sharp enough to

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excise corneal tissue” is misleading. How much is not sharp that the separator is needed for not excise corneal tissue during operation?

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 10-12 and 14-15 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Loomas et al (5,403,335) in view of Dybbs (5,308,355) and further in view of Ruiz et al (5,133,726)

Loomas discloses in figures 28,29, a surgical device which is suitable to separate the epithelial layer of a cornea from the cornea having the limitations as recited in the above listed claims including: a separator or a small spatula (see col. 10, lines 30-33) that is able to separate the epithelial layer as a disk and without rupturing the disk, where the device further has at least one of a ring 136, or a separator support 50 that fits in the groove 18, and where the separator is not sharp enough to excise corneal tissue during operation, where the ring includes a circumferential groove 52 on the side of the eye, and where the separator is provided by external rotating 64.

However Loomas is silent regarding the separator oscillating with a frequency ranging from about 10Hz to about 10KHz and rotating gears which placed on the separator support.

. Instead, Loomas indicates that the device comprises a separator or a small spatula. Dybbs teaches the separator oscillating with a frequency ranging from about 20 MHz. Ruiz teaches rotating gears 33,34 which placed on the separator support (see fig. 1).

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At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the separator oscillates with frequency ranging from about 10Hz to about 10KHz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re. Aller, 220F, 2d 454, 105 USPQ 233. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to modify Loomas with the microkeratome system including rotating gears as taught by Ruiz for providing movement of the separator during surgical operation. Regarding claims 10-11 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Loomas in view of Ulrich. Loomas discloses the invention substantially as claimed. However, Loomas is silent regarding the separator oscillation is provided by piezoelectric forces or electromagnetic forces on the separator. Instead, Loomas indicates that the device comprises a separator or a small spatula. Ulrich teaches the separator oscillation is provided by piezoelectric forces or electromagnetic forces on the separator (see Col. 1, lines 60-67 and col. 2, lines 45-51). At the time the invention was made, it would have been an obvious to one having ordinary skill in the art at the time the invention was made to modify Loomas by constructing the separator oscillation is provided by piezoelectric forces or electromagnetic forces on the separator as taught by Ulrich in order to provide a vibratory movement of the surgical device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ho Jackie can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

/Victor X Nguyen/
Examiner
Art Unit 3734

VN